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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,957	03/22/2005	Ian Flockhart	B0192.70056US00	8763

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EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
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1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/528,957

Applicant(s)

FLOCKHART ET AL.

Examiner

Rosalynd Keys

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/14/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

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DETAILED ACTION

Status of Claims

1. Claims 1-23 and 25 are pending.
Claims 1-23 and 25 are rejected.
Claim 24 is cancelled.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on July 14, 2006 has been considered by the examiner.

Content of Specification

4. The specification is objected to because it lacks a brief description of the drawing(s) as set forth in 37 CFR 1.74.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-13, 18-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1).

Webster et al. teach a cannabinoid extraction method comprising harvesting Cannabis

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composed of seed and chaff; separating the chaff from the seed; extracting the chaff with a solvent, thereby producing an extract; passing the extract, if desired, over a chromatographic column arranged to fractionate Δ^9 -THC out of the extract; and collecting the fractions lacking Δ^9 -THC from the column, thereby producing a whole hemp extract without the Δ^9 -THC. The collected fractions may be concentrated (see entire disclosure, in particular column 2, lines 5-23 and column 4, lines 26-48). The extraction solvent may be an organic solvent, which may be selected from a petroleum derived hydrocarbon or supercritical carbon dioxide (see column 2, lines 24-32). The cannabinoid may be selected from cannabidiol (see column 2, lines 56-63). In example I the chaff is pulverized and extracted with a solvent such as hexane. The liquid extract is separated from the solid component by filtration or other means and the extract may then be concentrated or dried and resuspended in a new solvent. In example II the second solvent for extraction is disclosed as a low molecular weight alcohol. In column 6, lines 16 and 17 Webster et al. teach that the cannabinoids may be crystallized.

Webster et al. differ from the instant claims in that Webster et al. do not disclose the purity of their cannabinoids. However, Webster et al. do suggest the claimed purity, since Webster et al. desire to obtain a purified cannabinoid which is free of Δ^9 -THC (see column 5, lines 3-25). Further, when claiming a purer form of a known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material. Ex parte Reed, 135 U.S.P.Q. 34, 36 (P.O.B.A. 1961), on reconsideration, Ex parte Reed, 135 U.S.P.Q. 105 (P.O.B.A. 1961). In the instant case the cannabidiol does not appear to have a property or utility not possessed by the cannabidiol of Webster et al.

Webster et al. further differ from the instant claims in the Webster et al. do not disclose the melting point of the crystalline cannabidiol.

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Adams discloses that one can obtain a pure crystalline cannabidiol from extracts of hemp (see column 1, lines 1-19). It is taught that the Cannabidiol has a melting point of 66-67° (see column 1, lines 25-27).

One having ordinary skill in the art at the time the invention was made would have found it obvious that the crystalline cannabidiol of Webster has a melting point of 66-67°, since Adams teaches that crystalline cannabidiol has a melting point of 66-67°.

Webster et al. further differ from the claims in that Webster et al. do not specifically disclose utilizing pentane as the solvent. However, Webster et al. do suggest the use of pentane, since Webster et al. disclose the use of a petroleum-derived hydrocarbon as a solvent (see column 4, lines 26-48, in particular lines 37 and 38).

Webster et al. further differ from the instant claims in that Webster et al. do not specifically disclose an initial extraction with liquid carbon dioxide followed by a secondary extraction with another solvent such as ethanol. Webster et al. do however teach that other solvents may be used as modifiers in combination with the supercritical fluid for targeted extraction of specific compounds (see example I). Webster et al. also teach that the extract may be suspended in another suitable solvent such as low molecular weight alcohol (see column 2, line 33-48).

Schmidt et al. teach that changing the polarity and hydrophilicity of the extracting solvent systems can modify the ratio of components in the Cannabis oil (see paragraph 0014).

One having ordinary skill in the art at the time the invention was made would have found it obvious to extract the Cannabis of Webster et al. with a combination of a supercritical fluid such as carbon dioxide and another solvent such as ethanol, since Webster et al. teach that combinations of solvent may be utilized for extraction. Further the skilled artisan would be motivated to select the combination of solvents in order to modify the ratio of components in the Cannabis oil, as taught by Schmidt et al.

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Webster et al. further differ from the claims in that Webster et al. do not teach a charcoal cleanup step.

Schmidt et al. teach that techniques known to the art such as steam distillation or activated charcoal filtration may optionally be utilized to further enrich the cannabinoid fraction of extracts (see paragraph 0018).

One having ordinary skill in the art at the time the invention was made would have been motivated to utilize a technique such as activated charcoal filtration, as taught by Schmidt et al., on the cannabinoid of Webster et al. in order to obtain a further enriched cannabinoid fraction for medicinal use.

10. Claims 1-23 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle et al. (WO 02/064109 A2) in view of Webster et al. (US 6,403,126 B1) and further in view of Schmidt et al. (US 2003/0017216 A1) and Adams et al. (US 2,304,669).

Whittle et al. teach a method of preparing a herbal drug extract comprising obtaining medicinal cannabis, chopping the cannabis, heating at a temperature of 100 to 150°C for sufficient time to decarboxylate acid form of cannabinoids to produce neutral cannabinoids, extraction with liquid carbon dioxide, removal of carbon dioxide to recover crude extract, winterization of crude extract in ethanol to precipitate unwanted waxes, removal of unwanted waxy material by cold filtration and removal of ethanol from the filtrate by thin film evaporation under reduced pressure (see example 17 on pages 63 and 64). Whittle et al. teach that one can obtain an extract from a chemovar of cannabis producing more than 90% of its cannabinoid as cannibidiol by supercritical fluid extraction of dried cannabis herb (see page 42, lines 9-13).

Whittle et al. differ from the instant claims in that Whittle et al. do not teach the use of a C5-C12 straight chain or branched alkane or a carbonate ester of a C1-C12 alcohol as the extraction solvent.

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Webster et al. teach a process for extraction of a cannabinoid wherein petroleum derived hydrocarbons are interchangeable as extraction solvents with supercritical carbon dioxide.

One having ordinary skill in the art at the time the invention was made would have found it obvious to substitute a petroleum-derived hydrocarbon, as taught by Webster et al., for the liquid carbon dioxide of Whittle et al., since Webster et al. teach that in a process for the extraction of cannabinoids one can use petroleum derived hydrocarbons and supercritical carbon dioxide interchangeably.

Whittle et al. further differ from the claims in that Whittle et al. do not teach treatment of the resulting solution with activated charcoal.

Schmidt et al. teach that techniques known to the art such as steam distillation or activated charcoal filtration may optionally be utilized to further enrich a cannabinoid fraction of extracts (see paragraphs, 0007 and 0018).

One having ordinary skill in the art at the time the invention was made would have been motivated to utilize a technique such as activated charcoal filtration, as taught by Schmidt et al., on the cannabinoid of Whittle et al. in order to obtain a further enriched cannabinoid fraction, which is valuable since the cannabinoid has medicinal use.

Whittle et al. further differ from the claims in that Whittle et al. their cannabidiol comprise less than 1% Δ^9 THC.

Webster et al. teach that Cannabis contains a high level of Δ^9 THC which is a psychoactive drug (see column 1, lines 15-43). Webster et al. teach that Δ^9 THC can be removed from the cannabinoid utilizing the steps of their invention.

One having ordinary skill in the art at the time the invention was made would have found it obvious that the Δ^9 THC is removed in the process of Whittle et al., since whittle et al. conduct some of the same steps utilized in the process of Webster et al.

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Whittle et al. do not disclose the melting point or CBD retention time of their cannabidiol. However, since the cannabidiol of Whittle et al. appears to be identical to the claimed cannabidiol it would inherently have the same melting point (66-67°C as taught in column 1, lines 25 and 26 of Adams et al.) and CBD retention time.

11. Claims 18-22 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adams (US 2,304,669).

Adams disclose a crystalline cannabidiol in pure form having a melting point of 66-67°C (see entire disclosure, in particular column 1, lines 1-54 and claim 3). The CBD retention time is inherently taught, since the substantially pure cannabidiol of Adams appears to be identical to the claimed substantially pure cannabidiol.

The cannabidiol of Adams appears to have the same purity as the instant cannabidiol, but if it is shown that it does not the claims are still unpatentable over the teachings of Adams because when claiming a purer form of a known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material. Ex parte Reed, 135 U.S.P.Q. 34, 36 (P.O.B.A. 1961), on reconsideration, Ex parte Reed, 135 U.S.P.Q. 105 (P.O.B.A. 1961). In the instant case the greater than 95% pure cannabidiol does not appear to have a property or utility not possessed by the cannabidiol of Adams.


Adams differ from claim 23 in that Adams do not make his cannabidiol by the same method. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 571-272-0639. The examiner can normally be reached on M, W & F 5:30-7:30 am & 1-5 pm; T & Th 5:30 am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Rosalynd Keys
Primary Examiner
Art Unit 1621

April 18, 2007